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AUG 30 2006REMARKS

Claims 6 and 16 have been cancelled. Thus, claims 1-5, 7, 8, 10-15 and 17-23 remain pending. Claims 1, 7, 8, 10-12, 17 and 19 have been amended. No new matter has been added. In view of the above amendments and the following remarks, it is respectfully submitted that all of the pending claims are allowable.

The Examiner has objected to the drawings, because reference numeral 22 shown in Fig. 1 is not mentioned in the specification. However, an amendment to the specification included in an Amendment filed 2/21/06 replaced paragraph [0012] of the specification with a new paragraph [0012] that states "[t]he balloon 12 is placed via a catheter 14 which may be inserted to the resection cavity 10 *through a trocar 22* from outside the patient's body through the incision made when the tumor was removed, or through a separate incision made with a scalpel at a later time." Therefore, it is respectfully requested that the objection to the drawings be withdrawn.

Claims 1-7, 12-17, 19, 20 and 22-23 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Winkler I (U.S. Pat. No. 6,413,204) in view of Houser (U.S. Pat. No. 6,632,196).

Claim 1 recites a device for preventing closure of a surgically created resection cavity within tissues of the body comprising "an insertion member having a distal end for insertion into a surgically created resection cavity and a proximal end which remains outside the resection cavity and a lumen extending between the proximal and distal ends, the insertion member having an outer diameter of approximately 5 FR to 10 FR" in combination with "an inflatable member deployable from the distal end of the insertion member, an inner chamber of the inflatable member being fluidly coupled to the lumen to receive an inflation fluid therefrom so that, when

the inflation fluid is supplied to the inflatable member, the inflatable member expands to a substantially spherical shape so that an outer surface of the inflatable member contacts the surrounding tissue and moves the surrounding tissue out of the resection cavity, *the inflatable member having a retention layer formed on the outer surface to retain a therapeutic agent and dispense the therapeutic agent at a selected rate.*”

In the final Office Action, the Examiner states that an outer polymeric film wall 36 of an inflatable outer spatial volume 34 described in Winkler I is “a retention layer formed on the outer surface of [an inflatable member] to retain a therapeutic agent and dispense the therapeutic agent at a selected rate,” as recited in claim 1. However, at no point does Winkler I disclose or suggest that the wall 36 may include a retention layer or any other structure for dispensing a therapeutic agent at a selected rate. Simply because the wall 36 is formed from a polymer film neither discloses nor suggests that the wall 36 is coated with a therapeutic agent or a retention layer. In fact, Winkler I states that the outer wall 36 is designed with a high burst strength so that, if an inner spherical wall 32 containing radioactive fluid burst, the outer wall 36 would prevent the radioactive fluid from seeping into the body. Thus, it is respectfully submitted that Winkler I neither discloses nor suggests, and, in fact, teaches away from “the inflatable member having a retention layer formed on the outer surface to retain a therapeutic agent and dispense the therapeutic agent at a selected rate,” as recited in claim 1.

It is respectfully submitted that Houser does not cure the deficiencies of Winkler I. Houser describes a dual balloon catheter in which a proximal balloon 260 may include perforations 266 for allowing drugs within a fluid used to expand the proximal balloon 260 to seep through a surface thereof. Houser never discloses or suggests that a retention layer or any other structure for dispensing a therapeutic agent at a selected rate is disposed on an outer surface of the proximal balloon 260. Therefore, it is respectfully submitted that Houser neither discloses

nor suggests "the inflatable member having a retention layer formed on the outer surface to retain a therapeutic agent and dispense the therapeutic agent at a selected rate," as recited in claim 1.

Therefore, applicants respectfully submit that neither Winkler I nor Houser, either alone or in combination, discloses or suggests "the inflatable member having a retention layer formed on the outer surface to retain a therapeutic agent and dispense the therapeutic agent at a selected rate," as recited in claim 1. Because claims 2-5 and 7 depend from, and, therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claim 12 recites a surgical tissue separator comprising "a substantially spherical expandable portion insertable in a surgically created body cavity" in combination with "a catheter portion adapted to position the expandable portion in the cavity, the expandable portion being deployable from the catheter portion" wherein "supplying an inflation fluid to the expandable portion via a lumen of the catheter portion expands the expandable portion into contact with inner surfaces of the cavity to prevent the inner surfaces from healing together, the catheter portion having an outer diameter of approximately 5 FR to 10 Fr" and "*the expandable portion includes a coating adapted to, when the expandable portion expands into contact with the inner surfaces of the cavity, time release a therapeutic compound to tissue surrounding the expandable portion.*"

As explained above, neither Winkler I nor Houser describes a coating formed on the expandable member for effecting a time release of a therapeutic compound. Thus, it is respectfully submitted that neither Winkler I nor Houser, either alone or in combination, discloses or suggests "the expandable portion includes a coating adapted to, when the expandable portion expands into contact with the inner surfaces of the cavity, time release a therapeutic compound to tissue surrounding the expandable portion," as recited in claim 12. Because claims

13-17, 19, 20 and 22-23 depend from, and, therefore include all of the limitations of claim 12, it is respectfully submitted that these claims are also allowable.

Claims 8, 18 and 21 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Winkler I in view of Houser in view of Winkler II (U.S. Pat. No. 6,537,194).

It is respectfully submitted that Winkler II does not cure the above-described deficiencies of Winkler I and Houser. That is, Winkler II describes a catheter 10 having an inflatable outer membrane 20 which allows an inflation fluid therein to seep through the outer membrane 20 and into surrounding tissue. There is no disclosure in Winkler II regarding a retention layer or coating formed on the outer membrane 20 for effecting a timed delivery of a therapeutic agent at selected rate. Thus, it is respectfully submitted that neither Winkler I nor Houser nor Winkler II, either alone or in combination, discloses or suggests "the inflatable member having a retention layer formed on the outer surface to retain a therapeutic agent and dispense the therapeutic agent at a selected rate," as recited in claim 1 or "the expandable portion includes a coating adapted to, when the expandable portion expands into contact with the inner surfaces of the cavity, time release a therapeutic compound to tissue surrounding the expandable portion," as recited in claim 12. Because claim 8 depends from claim 1 and claims 18 and 21 depend from claim 12, it is respectfully submitted that these claims are also allowable.

Claims 10 and 11 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Winkler I in view of Houser and in further view of Williams (U.S. Pat. No. 6,083,148).

It is respectfully submitted that Williams does not cure the above-described deficiencies of Winkler I and Houser. That is, Williams describes a catheter means 32 with an inflatable balloon 28 on a distal end thereof that is filled with a radioactive treatment fluid or a

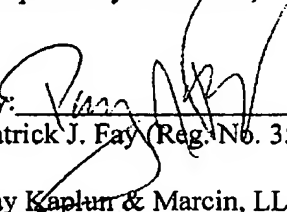
chemotherapy fluid. In the former instance, the balloon 28 is impermeable, while in the latter instance, the chemotherapy fluid seeps through a porous wall of the balloon 28. However, even in the case of the chemotherapy fluid, Williams neither discloses or suggests that a retention layer may be formed on the balloon 28 for dispensing the therapeutic agent at a selected rate. Thus, it is respectfully submitted that neither Winkler I nor Houser nor Williams, either alone or in combination, discloses or suggests "the inflatable member having a retention layer formed on the outer surface to retain a therapeutic agent and dispense the therapeutic agent at a selected rate," as recited in claim 1. Because claims 10 and 11 depend from claim 1, it is respectfully submitted that these claims are also allowable.

**CONCLUSION**

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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